

08/588,637



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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/588,637 01/19/96 BARBOUR

A 454313 2420
EXAMINER

020999
 FROMMER LAWRENCE & HAUG
 745 FIFTH AVENUE
 NEW YORK NY 10151

HM11/0324

ART UNIT	PAPER NUMBER
LORING, S	11

DATE MAILED:

03/24/98

This is a communication from the examiner in charge of your application.
 COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on AMB + DECL 1/13/98, DECL 2/20/98, IS 3/10/98 and 3/23/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10 and 12 is/are pending in the application.
 Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-10 and 12 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☒ The drawing(s) filed on 1/19/96 is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☒ Interview Summary, PTO-413 papers 9 and 10
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

SERIAL NUMBER 08/588,637
ART UNIT 1641

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1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1640, Art Unit 1641.

The Examiner in charge of this application has changed. Please address all future correspondence regarding SN 08/588,637 to Primary Examiner Susan A. Loring, Art Unit 1641.

2. The Amendment received January 13, 1998 (paper 7) requests amendment to the continuity information supported by a Declaration from Alan G. Barbour and Catherine J. Luke, as the named inventors of the instant application and further stating that Alan G. Barbour is a named inventor on US application SN 08/375,993, now US PAT 5,688,512 and US PAT 5,523,089 having priority to the Danish application 5902/88, filed October 24, 1988. Both copies of the signed Declaration have been received and entered (paper 5), as such this application has been granted priority to the Danish application 5902/88, filed October 24, 1988. The continuity paragraph contains the continuity information applicant has requested be entered by amendment (paper 7). It is noted that the continuity information which applicant has requested be entered is incomplete, based on the Declarations submitted by Alan Barbour and Catherine Luke. Applicant has failed to include pertinent information regarding SN 08/375,993, now US PAT 5,688,512. Amendment of the complete continuity information is required.

3. Applicants attention is directed to the first paragraph under Related Applications (page 1) of the instant specification. The Examiner has amended the specification to read: "Reference is made to US **PATENT 5,582,990**, filed October 3, 1994, **pending application Serial Nos. 08/137, 175**, filed October 26, 1993, 08/262,220, filed June 20, 1994, PCT/US95/07665, 08/373,455, filed January 17, 1995, **now abandoned**, PCT/US92/08697, and WO 90/04411, each of which is hereby incorporated by reference." The sections bolded refer to the changes made to the specification. Upon review of US PAT 5,582,990, it is noted that this first paragraph under related applications is not present. If applicant wishes to cancel the above noted information, they may amend the specification in their next response accompanied with a statement that the information being deleted is not pertinent to the patenting of the disclosed subject matter.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: change in priority, based on a change of ownership, requires a new oath, as the present oath does not specifically state the priority to all parent applications/patents.

5. Claims 1, 2, 6, 7, 8, and 12 have been amended and claim 11 has been canceled.

6. A telephone interview was held between Examiner Sidberry and Mr. Kowalski on February 10, 1998 regarding the cancellation of claim 5 without prejudice. This interview was held in anticipation of resolving all pending issues and placing this application into allowance. Another telephone interview (see attached interview summary) was held on March 23, 1998 to discuss an issue of obviousness-double patenting. This interview resulted in Mr. Kowalski requesting an office action with the rejection set forth before any decision could be made regarding the submission of a terminal disclaimer. In view of the two telephone interviews, it is suggested that Mr. Kowalski specifically cancel 5 along with responding to the following ODP rejection in the next submitted response, as claim 5 remains pending and additionally remains rejected under 35 USC 103 as being unpatentable over Bergstrom et al (US PAT 5,523,089) in view of Flavell et al (WO 92/00055), as set forth in the previous Office Action on page 6. For purposes of conciseness, the present Examiner has chosen not to repeat the rejection of record, as resolution of this rejection appears to have been resolved during the interview with Examiner Sidberry.

7. The drawings were objected to by the Draftsperson. These objections were mailed with paper no. 4 and can be found on PTO-Form 948. Figure 1A-1D are properly identified within the specification on pages 8-9, but the figure only denotes Fig. A, B, C, and D. Correction to properly identify each of the figures as 1A, 1B, 1C and 1D is required upon the submission of formal drawings.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an

actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-10 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7 of U.S. Patent No. 5,688,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to a method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising "mucosally" administering substantially pure OspA. US PAT 5,688,512 claims a method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising administering a vaccine comprising substantially pure OspA.

Effective June 8, 1995, any continuing application of a previously filed application will expire twenty years from the filing date of the earlier case. A terminal disclaimer is still required to overcome a nonstatutory double patenting rejection in a continuing application, even though both patents would expire on the same day anyway because of the twenty-year-term provisions under GATT/NAFTA. The reason is that the enforceability/common ownership provision of a terminal disclaimer under 37 CFR 1.321(C)(3) remains. A terminal disclaimer includes a provision that the later filed application which matures into a patent shall only be enforceable as long as the earlier and later filed patents are commonly owned. If and when the patents cease to be commonly owned, the patent containing the terminal disclaimer does not expire, but it becomes unenforceable. This would avoid the problem of an alleged infringer being harassed by two different parties with patents covering the same patentable invention (as defined in 37 CFR 1.601(n)).

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

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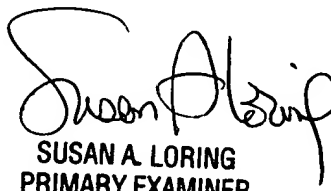
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action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan A. Loring whose telephone number is (703)308-3998.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


SUSAN A. LORING
PRIMARY EXAMINER
GROUP ~~1800~~
1641

March 23, 1998